

## **REMARKS/ARGUMENTS**

Applicants have studied the final Office Action dated April 30, 2008. It is submitted that the application, as it exists at present, remains in condition for allowance.

Claims 1 to 10, 17, 18, and 21 to 32 remain in the application. Claims 11 to 16 and 19 to 20 were canceled in a previous amendment to facilitate prosecution of the instant application. Reconsideration and allowance of the pending claims in view of the following remarks is respectfully requested.

In the Office Action, the Examiner:

- I. (Item 2) rejected claims 1 to 4, 7, 17, 18, 21 to 25, 28 and 32 under 35 U.S.C. § 102(b) as being fully anticipated by Nakao et al. (U.S. 5,222,961; hereinafter "Nakao"); and
- II. (item 4) rejected claims 5, 6, 8 to 10, 26, 27, and 29 to 31 under 35 U.S.C. § 103(a) as being unpatentable over Nakao and in further view of U.S. Patent No. 4,719,917 to Barrows et al. (hereinafter "Barrows") and as evidenced by U.S. Patent No. 5,002,562 to Oberlander.

### **I. (Item 2) Rejection under 35 U.S.C. § 102(b) to Nakao**

The Examiner rejected claims 1 to 4, 7, 17, 18, 21 to 25, 28, and 32 under 35 U.S.C. § 102(b) as being anticipated by Nakao (U.S. Pat. No. 5,222,961). Reconsideration of the application is requested.

As will be explained below, it is believed that the claims were patentable over the cited art in their original form and, therefore, the claims have not been amended to overcome the reference.

Before discussing the prior art in detail, it is believed that a brief review of the invention as claimed, would be helpful. Claims 1, 17, 21, 22, and 32 recite, *in relevant part*:

a first arm;

a second arm substantially parallel to said first arm;

a bridge connecting said first and second arms to form a substantially static U-

shaped structure; and

**EITHER:**

at least one deformable retainer extending from one end of said arms in a direction (claims 1, 21, 32).

**OR**

at least one deformable retainer extending from one of said arms (claims 17, 22).

As set forth in the instant application, the surgical clip is inserted by the clip applicator after the clip applicator jaws grasp and puncture the invaginated fundus. The tissue is plicated and the retainer and arms are caused to slide over the tissue for a distance. **Then, *only* the retainer portion of the surgical clip is plastically deformed to affix the clip to the fundus** (shown in Fig 13 below). Simply put, the language of claims 1, 17, 21, 22, and 32 provide that the two parallel arms and the bridge remain in the U-shaped form (in other words, they are “static”) and only the deformable retainer at the end of one or both of the arms can deform (in other words, it is “deformable”).

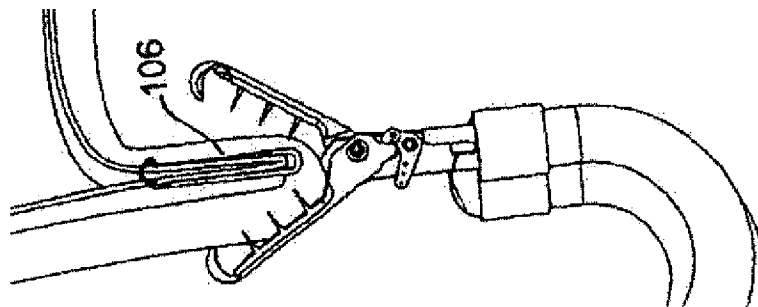


Fig. 13

As viewed, for example, in FIGS. 17 to 20 (which are reproduced below for the Examiner's convenience), the surgical clip of claim 1 shows the bridge connecting a first arm (e.g., 212, 312) to a substantially **parallel** second arm (e.g., 214, 314) in a **substantially static U-shaped structure**. As shown in FIG. 13 (immediately above), this U-shaped structure remains in this shape (i.e., “static”) while in use and even after applied to the tissue. Only the retainer (e.g., 222, 320, 322) is bent (i.e., “deformable”) after being applied to tissue.

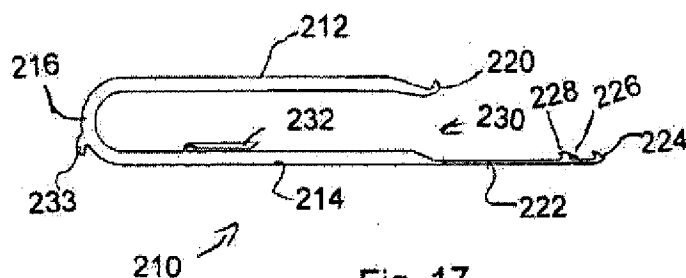


Fig. 17

The claimed surgical clip **maintains this static U-shaped structure** when exiting the jaws of the end effector and while the retainer is penetrating the tissue (for example, of the fundus). More specifically, the Detailed Description at col. 9, lines 11-16, provides that **the first and second arms, as well as the bridge** portion of the claimed clip are relatively stiff and **are not plastically** deformable within the limits of force applied to the arms during use. **Only the retainer section** of the clip (e.g., 222, 320, 322, 420, and 422) is **relatively easily plastically deformable** by the clip applier. *Id.*

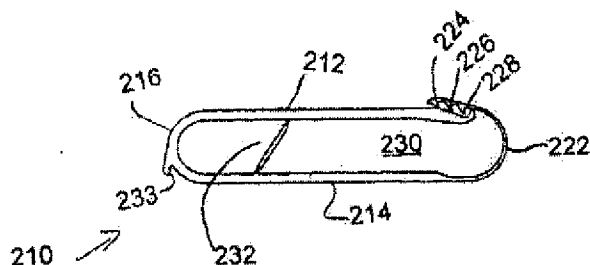
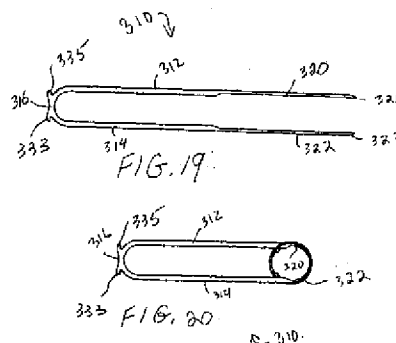


Fig. 18



In the Response to Arguments section on pages 3 to 4 of the final Office action, the Examiner's own language supports the conclusion that Nakao does not show the feature of the independent claims of the instant application. Specifically, the Examiner admits:

the clip of Nakao **has a state** in which the first and second arms are "substantially parallel". **Once the clip is applied**, the U-shaped bridge **will also have** a static U-shaped structure. Therefore, the clip of Nakao **has a static state** in which the second arm is substantially parallel to the first arm and the bridge is substantially

U-shaped. (Emphasis added by applicants.)

The Examiner's use of the word "state" undoes and makes impossible the conclusion that the Nakao clip is "static" as defined by Applicants of the instant application. This is because use of the word necessarily implies that there is another "state" in which the Nakao clip does not have "substantially parallel" arms and in which the Nakao clip does not have a "substantially U-shaped" structure of the arms and bridge. The independent claims state that the U-shape is "static." This means that the U-shape is not changeable according to the whim of a user. Rather, it is supposed to remain the same. By admitting that the Nakao clip only has "a state" in which the clip arms are "parallel"<sup>1</sup>, the Examiner is also admitting that the Nakao clip has another state in which they are not. This means that the Nakao arms move – a conclusion that is entirely supported by Nakao.

Both the specification and the claims do not define a **singular** time when the U-shaped arms and bridge is U-shaped and both do not define a **singular** time in which the arms are substantially parallel. Rather, Applicants state that the U-shaped structure of the arms and bridge and the parallel position of the arms are constant. The Examiner is attempting, in this Section 102 rejection, to make an entirely bendable Nakao clip (all portions thereof) be equal and identical to a substantially non-bendable U-shaped clip of the claimed invention. This comparison cannot stand, especially where the curved arms of the Nakao clip **are never parallel**.

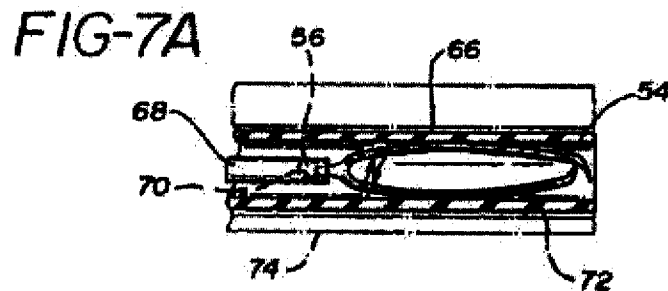
First, the Examiner admits that the Nakao staple is capable of being deformed because Nakao teaches that the staple is "made of a flexible material" as set forth in col. 9, lines 41-44, of Nakao. Accepted this admission as true, then, by definition, the Nakao staple cannot be static in any way and, in particular, cannot have a "substantially static U-shaped structure" as required by the independent claims of the instant application.

After a thorough examination of the Nakao disclosure, there is no way that the Nakao staple can

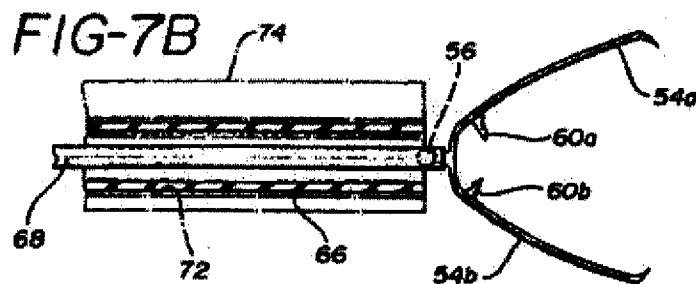
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<sup>1</sup> As set forth below, Nakao's curved arms can never be parallel because they are curved – one convex and one concave!

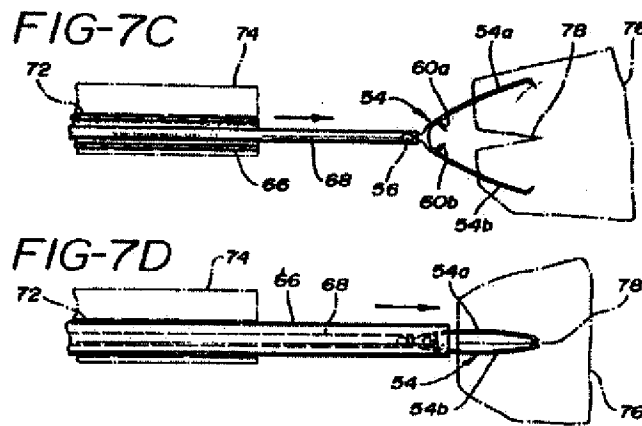
be said to have “substantially parallel” arms. As shown in Nakao’s FIG. 7A (reproduced immediately below), the Nakao staple is compressed pre-installation and, in this **state**, the arms cannot be considered parallel *because they are curved along their entire extent – one convexly and one concavely!*



Even if one were to imagine that these arms were “parallel” (a conclusion to which Applicants cannot agree), during the insertion operation, the arms of the Nakao staple deviate from the position of FIG. 7A -- **due to the built-in outward spring bias** – to place the arms in an open position, pictured in Nakao FIG. 7B below. Nakao at col. 9, lines 39-41, even explains that this open position inherently retains the two arms open at an angle to one another – meaning that **they are not parallel by design!**



The Nakao staple enters the position shown in FIG. 7A *only* when an inflexible tubular member 66 counteracts the outward-biased spring forces of the staple. This externally induced movement causes the barbs or hooks 60a, 60b of the finger elements 54a, 54b to interlock and actively hold the staple legs 54 in a closed configuration shown below in Nakao’s FIGS. 7C and 7D (*see also* Nakao at col. 10, lines 4-12). Nowhere does Nakao ever suggest that these legs 54a, 54b are parallel. In fact, Nakao discloses that the inherent properties of the legs 54a, 54b retain them in a non-parallel orientation.



The Nakao structure is distinctively different from the surgical clip of the present invention because the clip, *as claimed*, does not deviate from its “substantially parallel” arms and its “substantially static U-shaped” position, whether before, during, or after the implantation of the clip. The only part of the claimed invention that deforms is the retainer. See, e.g., FIGS. 13 and 20 (above).

Other features of the surgical clip of independent claims 1, 17, 21, and 32 include:

at least one deformable retainer extending from one end of the arms in a direction;  
and

the retainer having a length in that direction of at least approximately  $\pi$  or 2.5 times the distance between the arms when the arms are substantially parallel.

The Nakao clip cannot be said to suggest these features, let alone fully disclose them as required by Section 102.

The retainer portion of the claimed surgical clip is designed to be deformable and the arms and bridge are substantially not deformable. This deformable retainer has a specified length of  $\Pi$ -times-the-distance-between-the-arms “when the arms are substantially parallel.” (Emphasis added.) When the claimed clip is inserted through the jaws, only the retainer (not the arms or the bridge) is designed to plastically deform and pierce tissue. See, e.g., FIGS. 13 and 25. The

claimed length of the retainer allows for sufficient penetration into the tissue so that it can move towards the other arm, either to connect thereto in a lock (see FIG. 18) or to curve in a circle (see FIG. 20).

Nakao does not and cannot have the retainer as prescribed in the claims of the instant application. To the contrary, the Nakao staple moves at a hinge joint with “spring loaded jaws”. Nakao at col. 8, lines 47 to 48. Once the arms are inserted into the tissue, they are then physically moved together with the tubular member 66. Finally, the hooks 60a, 60b (present on the inside surface of the arms 32a, 32b) physically lock the staple arms 32a, 32b in place to physically overcome the open-oriented spring bias of the staple 32. With such a configuration, the portion of the Nakao staple *that penetrates inside the tissue does not deform* (see FIGS. 7C and 7D), entirely unlike the deformable retainers of the claimed surgical clip. Because it is the arms of the Nakao staple that enter the tissue, the Nakao staple cannot be said to have a retainer “extending from” the arms or from the end of the arms as set forth in these independent claims.

Even if the portion of the Nakao staple that is inserted into the tissue could be referred to as a “retainer” (a conclusion to which Applicants cannot agree), then the Nakao staple would not have the required parallel arms of the instant claims. More specifically, if the portion of the staple *inside the tissue* shown in FIGS. 7C and 7D is compared to the “retainer” of the claims in the instant application, then the Nakao staple become absolutely deficient in anticipating the rejected claims of the instant application. First, the remainder of the staple outside the tissue would have to include two parallel arms and these arms would have to be attached to a bridge to form a **static U-shaped structure**. What is left of the Nakao staple outside the tissue, however, is merely the staple’s hinge. As shown in the drawings, this hinge cannot be a static u-shaped structure because it would no longer be a “hinge” – by definition, a hinge moves. Second, the “arms” defined by the portion of the staple outside the tissue, are not parallel in any way. They are curved along their entirety and, by definition, cannot be considered parallel as required by the rejected claims.

Because the elements in independent claims 1, 17, 21, 22, and 32 of the instant application are neither taught nor disclosed by Nakao, the clip of Nakao cannot anticipate the present invention.

The dependent claims are believed to be patentable as well because they all are ultimately dependent on these independent claims. The Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. § 102(b) has been overcome.

**II. (Item 4) Rejection under 35 U.S.C. § 103(a) to  
Nakao in view of Barrows and Oberlander**

The Examiner rejected claims 5, 6, 8-10, 26, 27, and 29-31 under 35 U.S.C. § 103(a) as being unpatentable over Nakao and in further view of Barrows and as evidenced by Oberlander.

As set forth above, each of the independent claims is believed to be allowable. Because each of the rejected claims is dependent upon one of the allowable independent claims 1, 17, 21, 22, or 32, these dependent claims are allowable due to their dependency thereon.

**CONCLUSION**

Applicants acknowledge the continuing duty of candor and good faith to disclosure of information known to be material to the examination of this application. In accordance with 37 CFR §1.56, all such information is dutifully made of record.

Applicants respectfully submit that all of the grounds for rejection stated in the Examiner's Office Action have been overcome, and that all claims in the application are allowable. No new matter has been added. It is believed that the application is now in condition for allowance, which allowance is respectfully requested.

If an extension of time for this paper is required, petition for extension is herewith made.

It is believed that no fee is due with this Amendment. However, if any fees are due with respect to Sections 1.16 or 1.17, please charge to the deposit account of the undersigned firm, Acct. No. 503,836.

**PLEASE CALL** the undersigned if that would expedite the prosecution of this application.

Respectfully submitted,

Date: June 30, 2008

By:



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Gregory L. Mayback, Reg. No. 40,719  
Attorney for Applicants

**Mayback  
& Hoffman, P.A.**  
5722 S. Flamingo Road #232  
Fort Lauderdale, Florida 33330  
Office: 954.704.1599  
Fax: 954.704.1588  
[greg@mayback.com](mailto:greg@mayback.com)

GLM:cgm